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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,867	01/11/2001	Joseph Kevin Gogerty	1328	9583

27310 7590 10/30/2002

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER
FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/758,867	Gogerty
Examiner	**Group Art Unit**
FOX	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 8/22/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-32, 34-44, 47-49 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☑ Claim(s) 1, 24-8, 21, 23-27 is/are allowed.

☑ Claim(s) 3, 9-20, 22, 28-32, 34-44, 47-49 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The amendments of 22 August 2002 have overcome all outstanding objections and rejections under 35 USC 112 and 103, except as indicated below. However, new grounds of rejection under 35 USC 112, first and second paragraphs, are set forth below. The delay in prosecution is regretted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 11-13, 18-20, 22, 30-32 and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 22 remain indefinite for characterizing the male fertile plant of claim 2 [or claim 21] as male sterile. Since the claims are initially drawn to plants with defined characteristics and genotypes (such as claim 2) which exclude the presence of genetic factors conferring male sterility, it is confusing to characterize these plants as comprising additional genes. The dependent claims fail to further limit the claims from which they depend.

Claims 11 and 30, and dependent claims 12-13 and 31-32, are indefinite in their recitation of "plant of claim 2 [or 21] [which] contains...transgenes". Since the claims are initially drawn to plants with defined characteristics and genotypes (such as claim 2) which exclude the presence of transgenes, it is confusing to characterize these plants as comprising additional genes. The dependent claims fail to further limit the claims from which they depend.

Claims 18 and 47, and dependent claims 19-20 and 48-49, are indefinite in their recitation of "maize plants ... of claim 2 [or 21] further comprising...single gene conversions". Since the claims are initially drawn to plants with defined characteristics and genotypes (such as claim 2) which exclude the presence of additional introgressed genes, it is confusing to characterize these plants as now comprising additional genes. The dependent claims fail to further limit the claims from which they depend.

The Examiner acknowledges that Applicant has amended the claims as directed by the Examiner in the previous office action. However, it is now considered that the claims should be drafted in terms of methods of making a plant comprising transforming the exemplified plant of claim 2 or claim 21, and the products can be claimed in a product-by-process format. See the suggested claims faxed by Supervisory Patent Examiner Amy Nelson on 2 August 2002 in copending and commonly owned application Serial No. 09/490,666.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 9-20, 22, 28-32, 34-44 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11, 15-16, 30, 34-35, and dependents are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of making or using the transgenic plants. Claims 3, 18-20, 22 and 47-49 and dependents are broadly drawn to any "single gene conversion" plant comprising one or more traits including male sterility introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants. Claims 9-10, 12-17, 28-32, and 34-44 are also broadly drawn to any plant produced by crossing the exemplified inbred line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. These claims are also broadly drawn to methods of using the transgenic plants, single gene conversion plants, or descendant plants.

No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any single trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of

breeding partners, or the resultant progeny. Guidance has only been provided for a method of using the exemplified inbred in a single cross with another plant to produce an F1 hybrid.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 3, 9-20, 22, 28-32, 34-44 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 11, 15-16, 30, 34-35, and dependents are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of making or using the transgenic plants. Claims 3, 18-20, 22 and 47-49 and dependents are broadly drawn to any "single gene conversion" plant comprising one or more traits including male sterility introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants. Claims 9-10, 12-17, 28-32, and 34-44 are also broadly drawn to any plant produced by crossing the exemplified inbred line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. These claims are also broadly drawn to methods of using the transgenic plants, single gene conversion plants, or descendant plants.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits

whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of

alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant. See also Applicant's traversal of the art rejection on pages 7-8 of the amendment of 22 August 2002, where Applicant admits that outcrossing the exemplified inbred to another undisclosed plant is unpredictable.

Claims 14 and 43 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garing (U.S. Patent 6,034,304 filed January 1999), as stated in the last office action for claims 14, 33, 43 and 45-46.

Claims 1-13, 15-32, 34-42, 44 and 47-49 are deemed free of the prior art, given the failure of the prior art to teach or suggest the particularly claimed maize plants with their unique

complement of genotypic and mophological characteristics, or methods of using them, as argued in the amendment of 22 August 2002.

Claims 1-2, 4-8, 21 and 23-27 are allowed.

Applicant's arguments filed 22 August 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the art rejection is improper, given the failure of the prior art to teach or reasonably suggest the use of the exemplified inbred as a starting material in a process for the obtention of a maize plant which is a single generation away from the exemplified inbred.

The Examiner maintains that the neither the individual traits exhibited by the exemplified inbred nor the genes conferring these traits are unique to the exemplified inbred, either in occurrence or level of expression or means of inheritance. Rather, it is the entire genetic and morphological combination possessed by the exemplified inbred which is unique. Once this inbred is crossed with a multitude of non-exemplified and uncharacterized plants, even for a single generation, at least half of the genetic material of the inbred is lost. It is unclear and unlikely that the genetic material that remains in the first generation progeny retains the unique genetic and morphological complement of the exemplified inbred, particularly in view of the failure of Applicant to identify which individual genes or traits were unique to that inbred. Furthermore, since the *individual* traits exhibited by the exemplified inbred are not unique to the exemplified inbred, either by degree of expression nor genetic means of inheritance, a descendant of the exemplified inbred containing no genetic material from it could still exhibit these individual traits,

and could still possess the same genetic means for conferring these traits as did the exemplified inbred.

Furthermore, it is noted that both claims 14 and 43 are effectively drawn to multiple generations of outcrossing, rather than being drawn to a plant which is "a single generation away" from the exemplified inbred. Claims 14 and 43 specify multiple generations of selfing the initial outcross, wherein said multiple generations could result in the concentration of the germplasm from the non-exemplified plant. Furthermore, claim 43 is dependent upon claim 40, which does not specify the number of generations of outcrossing, given the open term "comprising" recited in the preamble.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 27, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638